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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,105	01/26/2001	Laurie J. Ozelius	0838.1001-009	7955

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,105	OZELIUS ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2003 and 14 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,8,10-12,14-28 and 31-34* is/are pending in the application.

4a) Of the above claim(s) *14-27* is/are withdrawn from consideration.

5)☒ Claim(s) *1,4,31 and 33* is/are allowed.

6)☒ Claim(s) *2,8,10-12,28,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *0803* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 2/20/03 and 5/14/03. The paper filed 2/20/03 amended claims 1, 2, 4, 8, 10, 12, 14, 15, 22, 24, and 28, and cancelled claims 29 and 30. The paper filed 5/14/03 amended claims 1, 2, 4, and 8, cancelled claims 3, 5-7, 9, and 13, and added claims 31-34. Thus, after entry of both amendments, claims 1, 2, 4, 8, 10, 11, 12, 14-28, and 31-34 are pending. Claims 14-27 are withdrawn from prosecution and thus, claims 1, 2, 4, 8, 10, 11, 12, 28, and 31-34 are examined herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Priority

2. Copendency has been established between the instant application and application serial number 09/461921, which was abandoned 2/25/01. It is noted, for the record, that nucleic acids consisting of SEQ ID NO: 30-39, 48, 49, 50, 51, 53, 54, 55, 56, and 89 are first disclosed in the 09/461921 application. Nucleic acids comprising or consisting of instant SEQ ID NO: 52, 88, and 90 are first disclosed in the instant application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 34 are further indefinite over the recitation "sequence of about 20 to 50 nucleic acids" because it is not clear if applicant intends for 20 to 50 different nucleic acids to be encompassed in the claim or a nucleic acid of 20 to 50 nucleotides. This rejection is maintained for amended claim 8 because the recitation remains in the claim and the rejection was not addressed by amendment or argument.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 8, 28, 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2 and 32 are drawn to isolated nucleic acid molecules comprising a polynucleotide sequence that specifically hybridizes under high stringency conditions to one of SEQ ID NO: 30-39, 48-56, and 88-90. The open claim language "comprising" means that the encompassed claim must have portion of that would hybridize under high stringency conditions to one of SEQ ID NO: 30-39, 48-56, and 88-90, but can also have any amount of additional sequence on the ends of the sequence. Claims 8 and 34 are drawn to isolated nucleic acids that comprise a polynucleotide of about 20 to 50 nucleotides, wherein the comprised 20 to 50

nucleotides specifically hybridize under high stringency conditions to one of SEQ ID NO: 30-39, 48-56, and 88-90. Again, the open claim language "comprising" means that for any of the encompassed nucleic acid must contain 20 to 50 nucleotides that would hybridize under high stringency to one of the recited sequences but may also have any additional sequences on the ends. For each particular sequence, the large genus encompassed by the claims is represented in the specification by a single species, that is the particular sequence which is disclosed.

Claim 28 is drawn to a "DYT1" gene comprising a mutation resulting in torsion dystonia. The instant specification only teaches one such gene and mutation that could be detected with the primers recited in claims 28, and this is the DYT1 gene encoding torsinA. Thus, for each of these broad claims, applicant has express possession of only one species in a genus which comprises hundreds of millions of different possibilities.

With regard to the written description, claims 2, 8, 28, 32, and 34 encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 2, 8, 32, and 34 include modifications by permitted by the hybridization language for which no written description is provided in the specification. The specification does not contain any particular guidance as to how these sequences can be modified and still retain their function, nor do the claims provide any structure/function relationship for the claimed nucleic acids. Furthermore, it is noted for 2, 8, 32, and 34 these claims encompass nucleic acids of unlimited length that are required to share very few nucleotides in common with the claimed nucleic acids. For claim 28, the only structure provided is that the claimed gene must be detectable by the recited primers. A multitude of possible changes are allowed from the disclosed sequence.

Claim 28 encompasses an unknown number of genes from humans and other mammal genes that are structurally limited in the claim only by the fact that they have to contain an undefined mutation or polymorphism and be detectable using SEQ ID NO: 30-39. Outside of

these two limitations the chemical structure of genes encompassed by claims 28-39 are structurally undefined.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid sequences of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

The instantly disclosed SEQ ID NO: 30-39, 48-56, and 88-90 have their utility in the ability to detect the instantly disclosed DYT1 gene which is associated with torsin dystonia. In the application at the time of filing, there is no record or description which would demonstrate conception of any proteins modified by addition, insertion, deletion, substitution or inversion with the disclosed sequences but possessing one or more nucleic acid differences such that a different nucleic acid sequence results which retains the function of the disclosed sequences.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 32 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Record AL158207 (GI: 7160605).

The GenBank record provides an isolated nucleic acid molecule comprising a polynucleotide sequence that specifically hybridizes under high stringency conditions to a sequence selected from the group consisting of SEQ ID NO: 52, 88, and 90. The nucleic acid provided in the GenBank record comprises isolated nucleic acids that are at least 90% identical to each of SEQ ID NO: 52, 88, and 90. For example, the sequence taught in the record comprises a polynucleotide with 100% local similarity to instant SEQ ID NO: 90 (nucleotides 74593-74792 are identical to SEQ ID NO: 90). As another example, the complement of nucleotides 85781-85405 of the GenBank record have 93.5% local similarity with instant SEQ ID NO: 88, as is exemplified in the following alignment. The alignment is of SEQ ID NO: 88 against the complement of the sequence found in the GenBank record. The sequence labeled "Qy" is SEQ ID NO: 88, and the sequence labeled Db is the complement of the sequence within the GenBank record.

```
  Query Match             75.0%;  Score 283.6;
  Best Local Similarity   93.5%;  Pred. No. 1.6e-71;
  Matches  359;  Conservative    0;  Mismatches   12;  Indels   13;  Gaps
6;

Qy       1 ctgggaaagacaaagccaatcaggagtggggaagaaaca-cggcaaaatgtagccacatt 59
           |||||||||||||||||||||||||||||||||||||||| |||||||||||||||||||
Db   85781 CTGGGAAAGACAAAGCCAATCAGGAGTGGGGAAGAAACAGCGGCAAAATGTAGCCACATT

Qy      60 tacagcccataaganagccagcaaagccgtctag----cctccaagcaccttgcgaaacc 115
           |||||||||||||| ||||||||||||||||||    ||||||||||||||||||||||
Db         TACAGCCCATAAGAAAGCCAGCAAAGCCGTCTAGACGCCCTCCAAGCACCTTGCGAAACC

Qy     116 tcaagtactgcggtctggtaagctcctggcccagaggggacggcggtccagggngccctc 175
           |||||||||||||||| |||||||||||||||||||||||||||||||| ||||||
Db         TCAAGTACTGCGGTCT-GTAAGCTCCTGGCCCAGAGGGGACGGCGGTCCAGGGAGCCCTC
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```
Qy    176 cctttgctggtcctgcctattctaaagccctggcccgnctccttcccgaaaagccccttg 235
          ||||||||||||||||||||||||||||||||||||| |||||||||||||||||||||||
Db          CCTTTGCTGGTCCTGCCTATTCTAAAGCCCTGGCCCGACTCCTTCCCGAAAAGCCCCTTG

Qy    236 gtgccactgccactgccaccantttgcnccccct-accccctgtnctgctcctcccacccca 294
          |||||||||||||||||||| ||||| ||||| |||||||| ||||||||||||||||||
Db          GTGCCACTGCCACTGCCACCAGTTTGCACCCCTAACCCCTGTGCTGCTCCTCCCACCCCA

Qy    295 aggcagatgcggnnggngaaaggaaacantttggtccctcctggtcggctcgnggaagac 354
          |||||||  |||     |||||||||| |||||||||||||||||||| | ||||||
Db          AGGCAGAGCCGG-----GAAAGGAAACAGTTTGGTCCCTCCTGGTCGGCT-GCGGAAGAG

Qy    355 tcctcaccatccttcctgtcttcc 378
          ||||||||||||||||||||| ||
Db          TCCTCACCATCCTTCCTGTCTCCC 85405
```

The alignment of SEQ ID NO: 52 against the GenBank sequence is as follows:

```
  Query Match             98.0%;  Score 392;  DB 9;  Length 169963;
  Best Local Similarity   98.8%;  Pred. No. 4.3e-117;
  Matches  395;  Conservative    0;  Mismatches    5;  Indels    0;  Gaps
0;

Qy      1 gaatatttacgagggtggtctgaacagtgactatgtccacctgtttgtggccacattgct 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  23727 GAATATTTACGAGGGTGGTCTGAACAGTGACTATGTCCACCTGTTTGTGGCCACATTGCA 23668

Qy     61 ctttccacatgcttcaaacatcaccttgtacaaggcaaggatggaagtttggaatccctt 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  23667 CTTTCCACATGCTTCAAACATCACCTTGTACAAGGCAAGGATGGAAGTTTGGAATCCCTT 23608

Qy    121 cctggatgtcatcgggtttggggtctctttgttgtgggatgagatttgggagttctatgt 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  23607 CCTGGATGTCATCGGGTTTGGGGTCTCTTTGTTGTGGGATGAGATTTGGGAGTTCTATGT 23548

Qy    181 tgaaatgagtgagcccggaaaacggttcatgtctcagttccccttggaaaggtgtagaag 240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  23547 TGAAATGAGTGAGCCCGGAAAACGGTTCATGTCTCAGTTCCCCTTGGAAAGGTGTAGAAG 23488

Qy    241 ttaagagtttgagatgcgtggagcagttaataccatcaaagctttgtggtgggttctgaa 300
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  23487 TTAAGAGTTTGAGATGCGTGGAGCAGTTAATACCATCAAAGCTTTGTGGTGGGTTCTGAA 23428

Qy    301 aatcggtccagtgagtatgtagggtcatgggatttagaggtggacatgatcaaatccat 360
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  23427 AATCGGTCCAGTGAGTATGTAGGGTCATGGGATTTTAGAGGTGGACATGATCAAATCCAT 23368

Qy    361 cttagagatcaacacatctcactatttttatttttcttat 400
          |||||||||||||||||||||||||| | || || |
Db  23367 CTTAGAGATCAACACATCTCACTATTTTTTTATTTTTTT 23328.
```

The portions of the GenBank sequence cited above would certainly hybridize with instant SEQ ID NO: 52, 88 and 90 under high stringency conditions.

Furthermore, each the GenBank sequence sequence comprises multiple polynucleotide sequences that are of about 20 to 50 nucleotides are nucleotides that specifically hybridize under high stringency conditions to SEQ ID NO: 52, 88, or 90.

It is noted that this reference is a 102(a) type reference against these claims because priority was not granted in this application to 09/461921 because the recited nucleic acids were not recited in the prior application.

9. Claims 2, 8, 28, 32, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ozelius et al. (Nature Genetics, Volume 17, 1997, pages 40-48).

Ozelius et al. teach provides an isolated nucleic acid molecule comprising a polynucleotide sequence would hybridize under high stringency conditions to a sequence selected from the group consisting of SEQ ID NO: 48-56 and 88-90 (Figure 1). Instant SEQ ID NO: 48-56 and 88-90 are nucleic acids that cDNA clones of DYT1 gene introns. DYT1 is the gene encoding torsinA, and is referred to in the paper by Ozelius et al. as DQ2. Ozelius et al. teach a series of cosmid contigs that are isolated nucleic acids containing genomic DNA from human chromosome 9q, and cosmid 29A5 is the cosmid that would contain the genomic DNA from which DQ2 is transcribed. Thus, cosmid 29A5 LA taught by Ozelius et al. would comprise the introns of the DQ2 gene and is therefore is an isolated nucleic acid molecule that inherently comprises a polynucleotide sequence that would hybridize under high stringency conditions to a sequence selected from the group consisting of SEQ ID NO: 48-56 and 88-90. Although Ozelius

et al. does not disclose the sequence of this cosmid, the cosmid taught by Ozelius et al. appears to be substantially identical to the nucleic acid claimed in claim 2.

With regard to claims 28, Ozelius et al. teach a gene comprising a gene mutation resulting in a dopamine-mediated disease in a mammal and could be detected by the method recited in the claims (see, for example Figure 5 and the DQ2 gene). Ozelius et al. teach that the sequence of the DQ2 gene is disclosed in GenBank AF007871 (p. 47). This sequence comprises instant SEQ ID NO: 31, 32, and 39, and thus could be detected by any one of these primers.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 10, 11, and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Ozelius et al. (WO 98/57984).

Ozelius et al. teach an isolated nucleic acid which comprises instant SEQ ID NO: 31, 32, and 39 (see SEQ ID NO: 5). The complement of nucleotides 153-172 of SEQ ID NO: 5 in Ozelius et al. are identical to instant SEQ ID NO: 31. Nucleotides 162-181 of SEQ ID NO: 5 in Ozelius et al. are identical to SEQ ID NO: 32. The complement of nucleotides 1295-1213 of SEQ ID NO: 5 in Ozelius et al. are identical to instant SEQ ID NO: 39.

Furthermore, Ozelius et al. teach that a preferred embodiment of their invention includes nucleic acid probes for the specific detection of the presence of torsin nucleic acid in a sample (p. 24, lines 18-21), that such nucleic acids should be or be complementary to 10 consecutive nucleotides (p. 24, lines 27-28), and they provide specific examples of such probes from their SEQ ID NO: 5 (p. 25). Ozelius et al. teach that one skilled in the art can readily design such probes based on the sequences that they disclose using methods of computer alignment and sequence analysis known in the art (p. 26, lines 14-18).

Ozelius et al. do not teach nucleic acid molecules consisting of SEQ ID NO: 31, 32, or 39. However, given the specific guidance provided by Ozelius et al. and the suggestion by Ozelius et al. to select probes from with and complementary to their SEQ ID NO: 5, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have selected additional probes from within the sequences taught by Ozelius et al. The ordinary practitioner would have been motivated to select such probes "for the specific detection of the presence of torsin nucleic acid in a sample (p. 24)" as taught by Ozelius et al. Although the probes of the instant invention are not specifically taught by Ozelius et al., they are considered functional homologues of the probes taught by Ozelius et al. in that they would be able to detect torsin nucleic acids in a sample, and as such, they are considered prima facie obvious in view of the prior art. Furthermore, in light of the teachings of Ozelius et al., it would have been prima facie obvious to have made the complement of any of the exemplified probes taught by Ozelius et al. in order to have provided additional probes for the detection of torsin nucleic acids.

Response to Remarks

With regard to the rejection in view of 112 1st paragraph, applicant argues that the claims, as amended, refer to sequences that hybridize under high stringency conditions to the disclosed intron sequences. However, this is not an entirely accurate construction of the claim. The claims encompass nucleic acid sequences that COMPRISE sequences that would hybridize to the disclosed sequences, and as such, encompass any sequence that has even a small portion that would hybridize to the disclosed sequences. Furthermore, applicant argues that one would know how to use the full scope of the claimed invention based on the disclosure of the intron sequences. Applicants suggest that with regard to written description they merely need to communicate to those skilled in the art that the claimed subject matter is intended to be part of their invention. The examiner disagrees. The court has made it clear that with regard to chemical compounds, the standard for written description is possession, not enablement or intent to claim. "While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not." In Re Ruschig, 379 F.2d 990, 995, 154 U.S.P.Q. 118, 123 (CCPA 1967). Furthermore, the court stated "Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." The Regents of the University of California v. Eli Lilly & Co., 43 U.S.P.Q.2d 1406 (Federal Circuit 1997). Thus, the question is not whether one could have used the claimed invention but whether or not applicant was in possession of the invention as claimed.

The amendment to claim 28 are not sufficient to overcome the rejection because the claims still encompass a multitude of genes that are not disclosed herein and that the specification has not provided description for, as discussed in the rejection.

The 102(a) rejection is maintained with regard to sequences that were not disclosed in the priority application.

With regard to the remaining art rejections, applicants are not entitled to the earliest filing date of June 19, 1997 because the claimed intronic sequences were not provided in the earliest filed application. In fact, they were not described until the 09/461921 application, filed 12/15/99, or the instant application, filed 1/28/01, and thus the rejection under 102(b) is maintained as noted in this office action.

The 102 rejection in view of WO 98/57984 has been withdrawn in light of the amended claims.

Applicant argues with regard to the 103 rejection of claims 10, 11, and 12 that because the teachings of WO 98/57984 do not include a teaching of the intron/exon boundaries it would not have been obvious to make the claimed primers. However, this is not persuasive. As discussed in the rejection, the WO document teaches a nucleic acid that comprises each of SEQ ID NO: 31, 32, and 39, and specifically provides guidance as to how to select primers and probes from within the nucleic acid that comprises these sequences. Thus, for the reasons stated in the rejection, one would have been guided and motivated to select any probes or primers from within SEQ ID NO: 5 as taught in the WO document, using the guidance provided in the document. Knowledge of the intron/exon boundaries would not have been necessary to select the claimed

sequences as probes or primers for the detection of SEQ ID NO: 5 taught in the document, and these primers and probes are clearly suggested by the document.

The request for rejoinder will be revisited in the event that the application is in condition for allowance.

Conclusion

12. Claims 1, 4, 31, and 33 are allowed. The prior art does not teach or suggest isolated nucleic acids consisting of the recited nucleic acids. The closest prior art is cited of record, and although this prior art teaches nucleic acids comprising one or more of these sequences, the prior art does not specifically teach or suggest isolated nucleic acids that consist of these intronic sequences of the recited fragments of these intronic sequences. Thus, these claims are free of the prior art.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

Juliet C. Switzer
AU 1634

August 9, 2003

GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600